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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/935,703	08/24/2001	Yanggu Shi	PT050P1	9669

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EXAMINER

STEADMAN, DAVID J

ART UNIT PAPER NUMBER

1652

DATE MAILED: 05/01/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/935,703

Examiner

David J. Steadman

Applicant(s)

SHI ET AL.

Art Unit

1652

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-22 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-22 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____.

Art Unit: 1652

DETAILED ACTION

Application Status

- [1]** Claims 1-22 are pending in the application.

Election/Restrictions

- [2]** Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I.** Claim(s) 1-10, 14, and 15, drawn to an isolated nucleic acid, vector, host cell, and a method of producing a polypeptide, classified in class 435, subclass 196.
- II.** Claim(s) 11, 12, and 16, drawn to an isolated polypeptide, classified in class 435, subclass 196.
- III.** Claim(s) 13, drawn to an isolated antibody, classified in class 530, subclass 387.9.
- IV.** Claim(s) 17, drawn to a method for preventing, treating, or ameliorating a medical condition by administering a polynucleotide, classified in class 514, subclass 44.
- V.** Claim(s) 18, drawn to a method of diagnosing a pathological condition or a susceptibility to a pathological condition by determining the presence or absence of a mutation in a polynucleotide, classified in class 435, subclass 6.
- VI.** Claim(s) 19, drawn to a method of diagnosing a pathological condition or a susceptibility to a pathological condition by determining the presence or amount of expression of a polypeptide, classified in class 435, subclass 19.
- VII.** Claim(s) 20 and 21, drawn to a method of identifying a binding partner of a polypeptide or a method of screening for molecules which modify activities of a polypeptide, classified in class 435, subclass 19.
- VIII.** Claim(s) 22, drawn to for preventing, treating, or ameliorating a medical condition by administering a polypeptide, classified in class 514, subclass 2.

Art Unit: 1652

[3] If applicant should elect one of Groups I, IV, or V, restriction to one of the following is also required under 35 USC 121. Therefore, if applicant elects any of Groups I, IV, or V, election is required to one of inventions a)-e).

- a) A nucleic acid encoding SEQ ID NO:7 including SEQ ID NO:2.
- b) A nucleic acid encoding SEQ ID NO:8 including SEQ ID NO:3.
- c) A nucleic acid encoding SEQ ID NO:9 including SEQ ID NO:4.
- d) A nucleic acid encoding SEQ ID NO:10 including SEQ ID NO:5.
- e) A nucleic acid encoding SEQ ID NO:11 including SEQ ID NO:6.

[4] If applicant should elect one of Groups II, VI, VII, or VIII, restriction to one of the following is also required under 35 USC 121. Therefore, if applicant elects any of Groups II, VI, VII, or VIII, election is required to one of inventions f)-j).

- f) SEQ ID NO:7.
- g) SEQ ID NO:8.
- h) SEQ ID NO:9.
- i) SEQ ID NO:10.
- j) SEQ ID NO:11.

[5] If applicant should elect Group III, restriction to one of the following is also required under 35 USC 121. Therefore, if applicant elects Group III, election is required to one of inventions k)-o).

- k) An antibody that binds SEQ ID NO:7.
- l) An antibody that binds SEQ ID NO:8.
- m) An antibody that binds SEQ ID NO:9.
- n) An antibody that binds SEQ ID NO:10.
- o) An antibody that binds SEQ ID NO:11.

[6] The inventions are distinct, each from the other because:

Art Unit: 1652

[7] The nucleic acids of Groups a)-e) are structurally distinct encoding structurally distinct polypeptides that elicit different antibodies and no single nucleic acid of Groups a)-e) would render the others obvious to one of ordinary skill in the art.

[8] The polypeptides of Groups f)-j) are structurally distinct and elicit different antibodies and no single polypeptide of Groups f)-j) would render the others obvious to one of ordinary skill in the art.

[9] The antibodies of Groups k)-o) bind structurally distinct polypeptides and no single antibody of Groups k)-o) would render the others obvious to one of ordinary skill in the art.

[10] The polynucleotide of Group I, the polypeptide of Group II, and the antibody of Group III each comprises a chemically unrelated structure capable of separate manufacture, use and effect. The polynucleotide of Group I has other utility besides encoding polypeptides such as a hybridization probe, the polypeptide of Group II can be made by another method such as purification from the natural source or chemical synthesis, and the antibody of Group III can be generated using a protein, other than the protein of Group II, such as a protein purified from the natural source or a chemically synthesized protein.

[11] The polynucleotide of Group I and the method of Group IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polynucleotide of Group I can be used for protein expression.

[12] The polynucleotide of Group I is unrelated to the method(s) of Groups V-VIII as it is neither used nor made by the method(s) of Groups V-VIII.

[13] The polypeptide of Group II is unrelated to the method(s) of Groups IV and V as it is neither used nor made by the method(s) of Groups IV and V.

[14] The polypeptide of Group II and the methods of Groups VI-VIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially

Art Unit: 1652

different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the polypeptide of Group II can be used as an antigen for the production of an antibody.

[15] The antibody of Group III is unrelated to the method(s) of Groups IV, V, VII, and VIII as it is neither used nor made by the method(s) of Groups IV, V, VII, and VIII.

[16] The antibody of Group III and the method of Group VI are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the antibody of Group III can be used as an affinity purification reagent for purifying the polypeptide of Group II.

[17] The methods of Groups IV-VIII are independent as they comprise different steps, utilize different products, and yield different results.

[18] MPEP § 803 sets forth two criteria for restricting between patentably distinct inventions – 1) the inventions must be independent or distinct and 2) there must be a serious burden on the examiner. MPEP § 803 states, "For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation either separate classification, separate status in the art, or a different field of search as defined in MPEP § 808.02". Because the inventions of Groups a)-o) and I-VIII are distinct for the reasons given above and each of the inventions requires a separate patent and non-patent literature and sequence search, restriction for examination purposes is proper.

[19] Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

[20] Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of

Art Unit: 1652

inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Steadman, whose telephone number is (703) 308-3934. The Examiner can normally be reached Monday-Thursday from 6:30 am to 5:00 pm. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Ponnathapura Achutamurthy, can be reached at (703) 308-3804. The FAX number for this Group is (703) 308-4242. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Art Unit receptionist whose telephone number is (703) 308-0196.

David J. Steadman, Ph.D.
Patent Examiner
Art Unit 1652

5/1/03

